

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: ALLEN et al.

Serial No.: 09/816,790

Filed: March 22, 2001



Group Art Unit: 1633

Examiner: Qian, Celine X.

Atty Docket No.: R-855

For: TRANSGENIC MICE CONTAINING SULFOTRANSFERASE GENE DISRUPTIONS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed December 03, 2001, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, Invention I (claims 1-10 and 17-21), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a sulfotransferase gene, a sulfotransferase gene knockout non-human animal and a method of making said non-human-animal.

In the restriction, the Examiner asserts that claims 1-25 are drawn to six distinct subjects, grouped as: Invention I (claims 1-10 and 17-21), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a sulfotransferase gene, a sulfotransferase gene knockout non-human animal and a method of making said non-human-animal; Invention II (claims 11 and 13), drawn to a method of identifying an agent that modulates sulfotransferase gene expression; Invention III (claims 12, 14, and 23), drawn to a method of identifying an agent that modulates sulfotransferase gene function; Invention IV (claims 16 and 25), drawn to an agent that modulates sulfotransferase gene expression or function; Invention V (claims 22 and 24), drawn to a method of identifying an agent that ameliorates a behavior associated with a disruption in a sulfotransferase gene; and Invention VI (claim 25), drawn to an agent that modulates a behavior associated with sulfotransferase disruption. The Examiner also

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asserts that claim 15 is generic to groups II and III and that claim 25 is generic to groups IV and VI. Applicants respectfully request reconsideration and withdrawal of the requirement.

Specifically, the Examiner asserts that the claims of Invention I and Invention II are patentably distinct in that the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operations. The Applicants disagree with the Examiner's conclusion in that the claims of Invention I are related to the methods of Invention II. Therefore, a separate search or examination that would seriously burden the Examiner would not be required.

The Examiner also asserts that the claims of Invention I and Invention III are patentably distinct in that the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's conclusion in that the compositions and methods recited in the claims of Invention I are related to the methods recited in the claims of Invention III. Therefore, a separate search or examination that would seriously burden the Examiner would not be required.

It is also asserted by the Examiner that the claims of Invention I and Invention IV are patentably distinct in that the inventions are drawn to materially different compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the claims of Invention I are related to the sulfotransferase expression or function modulator recited in the claims of Invention IV. A search and examination of these claims can be made without additional burden on the Examiner.

The Examiner also asserts that the claims of Invention I and Invention V are patentably distinct in that the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the claims of Invention I are related to the methods recited in the claims of Invention V. A search and examination of these claims, therefore, can be made without additional burden on the Examiner.

The Examiner further asserts that the claims of Invention I and Invention VI are patentably distinct in that the inventions are drawn to materially different compositions and methods that are not directly related. The Applicants disagree with the Examiner's assertion in that the compositions and methods recited in the claims of Invention I are related to the agent

recited in the claim of Invention VI. A search and examination of these claims can be made without serious burden to the Examiner.

The Examiner also asserts that the claims of Invention II and Invention III are patentably distinct in that the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention II and the methods recited in the claims of Invention III require the same starting materials and the same or related modes of operation. More particularly, claim 11 of Invention II and claims 12 and 23 of Invention III both require that a non-human transgenic animal comprising a disruption in a sulfotransferase gene be provided. The claims also recite modulation of the gene by an agent. Any search or examination of the prior art conducted on these aspects, *i.e.* a non-human transgenic animal comprising a disruption in a sulfotransferase gene and modulation of this gene, would produce results that would comprise modulation of the expression or modulation of the function of a sulfotransferase gene. The same applies to claim 13 of Invention II and claim 14 of Invention III as directed to cells and the modulation of the expression and function of a sulfotransferase gene. Thus, the additional burden of a separate search or examination would not be required.

With respect to Invention II and Invention IV, related as process of making and product made, respectively, the Examiner asserts that the inventions are patentably distinct because the agent of Invention IV can be identified by a method other than the methods recited in the claims of Invention II. The Applicants disagree in that the agents recited in the claims of Invention IV are related to the methods recited in the claims of Invention II. A search and examination of these claims can be made without additional burden on the Examiner.

The Examiner asserts that the claims of Invention II and Invention V are patentably distinct in that the inventions are drawn to methods that require different starting materials and modes of operations. The Applicants disagree with the Examiner's conclusion as the methods recited in the claims of Invention II and the methods recited in the claims of Invention V require the same or similar starting materials. More particularly, both groups of claims recite administering an agent to a transgenic mouse comprising a disruption in a sulfotransferase gene. Moreover, the methods recited in the claims of Inventions II and V require the same or closely related modes of operation. Specifically, the claims of both groups are drawn to methods of

identifying an agent that modulates a sulfotransferase gene, in which the steps or modes of operation of determining whether the agent modulates a sulfotransferase gene are the same or closely related. Therefore, a search and examination of these claims can be made without serious burden to the Examiner.

The Examiner further asserts that the claims of Invention II and Invention VI are patentably distinct in that the inventions are drawn to methods and compositions that are not directly related and that the methods of Invention II cannot produce the agent of Invention VI. The Applicants disagree with this assertion in that the methods of identifying an agent recited in the claims of Invention II can produce the agent recited in claim 25 of Invention VI, and thus the inventions are related. A search and examination of the claims of Inventions II and VI, therefore, can be made without serious burden on the Examiner.

The Examiner asserts that the claims of Invention III and Invention IV, related as process of making and product made, respectively, are patentably distinct because the agents of Invention IV can be identified by a method other than the methods of Invention III. The Applicants disagree with the Examiner's assertion in that the agents of Invention IV are related to the methods recited in the claims of Invention III. Thus, a search and examination of the claims can be made without serious burden on the Examiner.

The Examiner also asserts that the claims of Invention III and Invention V are patentably distinct as the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention III and the methods recited in the claims of Invention V require the same or similar starting materials. For example, claims 12 and 23 of Invention III and claims 22 and 24 of Invention V both require a non-human transgenic animal or a transgenic mouse comprising a disruption in a sulfotransferase gene. Further, claim 23 of Invention III and claims 22 and 24 of Invention V are drawn to methods of identifying an agent that modulates a sulfotransferase gene, in which the steps or modes of operation of determining whether the agent modulates a sulfotransferase gene are the same or closely related, for example, both groups of claims recite modulation of a behavior. For instance, in the above mentioned claims, the behaviors recited include aggressive, hyperactive, increased activity or decreased anxiety. However, any search or examination of the prior art should reveal results related to any behavior

or phenotype. Therefore, serious burden on the Examiner would not result from a search and examination of the claims of Inventions III and V.

The Examiner further asserts that the claims of Invention III and Invention VI are patentably distinct in that the inventions are drawn to methods and compositions that are not directly related and that the methods of Invention III cannot produce the agents of Invention VI. The Applicants disagree with the Examiner's conclusion in that the method recited in the claims of Invention III comprising the step of determining whether the agent modulates sulfotransferase expression, wherein the agent has an affect on a behavior can produce the agent that ameliorates a behavior as recited in the claims of Invention VI. Therefore, a search and examination of the claims can be made without serious burden on the Examiner.

The Examiner further concludes that the claims of Invention IV and Invention V are patentably distinct in that the inventions are drawn to compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV and the methods recited in the claims of Invention V are related. Thus, a search and examination of these claims can be made without serious burden on the Examiner.

The Examiner also concludes that the claims of Invention IV and Invention VI are patentably distinct in that the inventions are drawn to materially distinct compositions. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV and the agent recited in claim 25 of Invention VI are related. A search and examination of these claims can be made without serious burden to the Examiner.

Finally, with respect to the claims of Invention V and Invention VI, related as process of making and product made, respectively, the Examiner concludes that the inventions are patentably distinct because the agent of Invention VI can be identified by a method other than the methods recited in the claims of Invention V. The Applicants disagree with the Examiner's conclusion in that the methods of Invention V and the agent of Invention VI are related. Thus, a separate search or examination that would seriously burden the Examiner would not be required.

Although the Applicants have provisionally elected Invention I for the purposes of advancing prosecution of the present application, Applicants contend for the foregoing reasons

that the restriction requirement is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of the requirement.

A Petition for the Extension of Time for response to the Office Action for a period of one month from January 2, 2002 up to and including February 4, 2002 is submitted concurrently herewith.

Respectfully submitted,

Date: February 4, 2002

Mariette A. Lapis 44,202
(Signature) (Reg. No.)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICECommissioner for Patents
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FEB 14 2002In re PATENT APPLICATION ofInventors: **PHILLIPS et al.**Appln. No.: **09/816,790**Filed: **March 22, 2001**Title: **Transgenic Mice Containing Sulfotransferase
Gene Disruptions**Group Art Unit: **1633**Examiner: **Qian, C. X.**Docket/Order #: **R-855**Deposit Acct: **50-1271**Customer #: **26619**Date: **February 4, 2002**

RESTRICTION REQUIREMENT TRANSMITTAL

Sir:

Please file the enclosed response to restriction requirement in the above-identified application. The signature below is to be treated as the signature to the enclosure in absence of a signature thereto.

FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity previously claimed	Claims remaining	Highest # paid for	Present Extra	Small Entity	Add'l Fee	Fee Code
2. Total Claims	16	minus 33	= 0	x \$9. =	+ 0	203
3. Independent Claims	07	minus 14	= 0	x 42. =	+ 0	202
4. If amendment enters multiple dependent claim(s) for the first.....	add	+	\$140. =	+		204
5. Original due date: January 2, 2002						
6. Petition is hereby made to extend the due date to cover the date this response is filed, for which the requisite fee is enclosed				1 mo \$55 2mos \$200 3mos \$460 =		215 216 217
7. Enter any previous extension fee paid and (subtract)-						
8. Total fee for extension of time:				+\$55		
9. If Terminal Disclaimer is enclosed, add Rule 20(d) official fee.....				+ \$55. =	+	248
10. If IDS enclosed requires Official Fee, add				+ \$180. =	+	126
or if Rule 97(d) Petition, add				+ \$130. =	+	122
11. After-Final Request Fee per Rules 129(a) and 17(r).....				+ \$370. =	+	246
12. No. of additional inventions for examination per Rule 129(b):.....				ea x \$370. =	+	249
13. Petition fee for					+	
TOTAL FEE: <input checked="" type="checkbox"/> CHARGE AUTHORIZATION <input type="checkbox"/> ENCLOSED =						\$55

Charge Statement: The Commissioner is hereby authorized to charge any missing or insufficient fees relative to this application, or credit any overpayment, to our Account/Order Nos. above, for which purpose a duplicate copy of this sheet is enclosed.

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I certify that this paper and listed enclosures are being deposited with the U.S. Post Office "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the above date, addressed to Commissioner for Patents, BOX AMENDMENT, Washington, D.C. 20231

Joyce Vogel